Applicant: Robert N. Hamlin

Serial No.: 08/692,314 Filed

: August 5, 1996

Page

Attorney's Docket No.: 10527-003005 Client's Ref. No.: PC7558D-U.S.

REMARKS

Applicant amended claims 206, 208, 210, 211, 213, and 215, and added new claim 218. Applicant amended the claims to recite a multilayer balloon including an extruded tensile layer having a first polymeric material of polyetheretherketone (PEEK) or polyetherketone (PEK). Claims 206-218, of which claim 206 is the only independent claim, are presented for examination.

The Examiner rejected claims 206-217 under 35 U.S.C. §112, first paragraph, as containing subjected matter which was not described in the specification. In particular, while the rejection acknowledged that Applicant's disclosure supports a claim reciting a tensile layer having PEEK or PEK, the rejection asserts that Applicant's disclosure does not clearly support providing a PEEK or PEK layer as an inner layer, or a layer inside of a second layer or a bonding layer. The rejection reasons that since PEEK and PEK are disclosed as materials included in the tensile layer, and the tensile layer is described as forming an outer layer only, then PEEK and PEK can only be included in the outer layer. But this reasoning is inconsistent with Applicant's disclosure, which explicitly discloses that a material can be used both in the tensile layer and in the inner layer.

Indeed, the specification expressly illustrates the use of tensile material as an inner bonding layer. Polyvinyl chloride (PVC) is among a list of examples, including PEEK and PEK, that can be used in the tensile layer. (See, e.g., page 3, lines 14-36, of the specification.) The specification describes a balloon having PVC as an inner layer and PET as an outer layer. (See, e.g., page 7, line 20, to page 9, line 15, of the specification.) The balloon's inner layer of PVC can be bonded to a catheter body:

While the PVC layer 48 adds little to the burst strength of the composite, it does facilitate the attachment of the balloon to the exterior of the tubular catheter body. (See, page 9, lines 13-15, of the specification.)

Thus, the reasoning in the rejection that a tensile layer material can only be used in the outer layer is inconsistent with Applicant's disclosure. A person of ordinary skilled would clearly

Applicant: Robert N. Hamlin Serial No.: 08/692,314

Filed : August 5, 1996

Page

Attorney's Docket No.: 10527-003005 Client's Ref. No.: PC7558D-U.S.

recognize that Applicant had possession of a multilayer balloon having PEEK or PEK in the outer layer or, similar to PVC, in the inner layer.

Applicant requests that the rejection be reconsidered and withdrawn. Applicant believes that the claims are in condition for allowance, which action is requested.

Attached is a marked-up version of the changes being made by the current response. Enclosed a Petition for Extension of Time and the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: MAY 6, 2002

Reg. No. 42,934

Fish & Richardson P.C. 225 Franklin Street Boston, Massachusetts 02110-2804

Telephone: (617) 542-5070 Facsimile: (617) 542-8906

20402621.doc

Applicant: Robert N. Haralin Serial No.: 08/692,314

Filed

MAY 1 4 2002

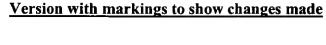
: August 5, 1996

Page : 5



Attorney's Docket No.: 10527-003005

Client's Ref. No.: PC7558D-U.S.



COPY OF PAPERS ORIGINALLY FILED

the claims:

Please amend the following claims:

(Amended) A medical balloon catheter comprising a multilayer balloon having

[a first] an extruded tensile layer comprising a first polymeric material selected from a group consisting of polyetheretherketone (PEEK) and polyetherketone (PEK), and a second extruded layer, wherein the first layer comprises a first polymeric material selected from the group consisting of polyetheretherketone (PEEK) and polyetherketone (PEK), and the second layer comprises comprising a second polymeric material different from the first polymeric material.

- (Amended) The medical balloon catheter of claim 207 wherein the [first] tensile layer consists essentially of polyetheretherketone (PEEK).
- (Amended) The medical balloon catheter of claim 209 wherein the [first] tensile layer consists essentially of polyetherketone (PEK).
- (Amended) The medical balloon catheter of claim 206 wherein the balloon is the product of coextruding the [first] tensile and second layers.
- (Amended) The medical balloon catheter of claim 206 wherein the [first] tensile layer is biaxially oriented.
- (Amended) The medical balloon of claim 214 wherein the adhesion layer is disposed toward the interior of the balloon relative to the [second] tensile layer, which is disposed toward the exterior.

Please add the following new claim:

(New) The medical balloon of claim 206, wherein the tensile layer is an outer 218. layer of the balloon.

RECEIVED

MAY 2 4 2002

GROUP 3600

TC 1700